

Acyclovir, Fine powder			
No. : RPB 175	Rev : 02	Eff. date : 180213	Sign : <i>Ø</i>

1 Quality

- 1.1 USP 37, 2014
- 1.2 Inhouse Indofarma

2 Additional Requirements

- 2.1 Particle size : Pass mesh 120 (125 µm) NLT. 40%
Pass mesh 80 (180 µm) NLT. 95%
- 2.2 Arrival Date : NMT. 12 months from manufacturing date

3 Certificate of Analysis from Manufacturer

To be stated on the certificate

- 3.1 Manufacturer name and address
- 3.2 Product name, batch/lot number
- 3.3 Results of test and assays
- 3.4 Compliance with USP 37
- 3.5 Quality designation
- 3.6 Date of manufacturing, expiration (year-month) and date of released (year- month-day)
- 3.7 Approval/signature of QA/QC responsibility

4 Attached update Good Manufacture Practise Certificate

5 Package

Cardboard drum @ 25 kg, with original seal (inside and outside) from manufacture.
To be stated on goods, label original from manufacture at primary secondary package each
Preserve in tight containers.

6 Labeling

To be stated on goods **label original from manufacturer**, packing list and invoice :

- 6.1 Name of manufacturer and address
- 6.2 Product name, batch/lot number, manufacturing and expiration date
- 6.3 Quality designation
- 6.4 Gross/net weight
- 6.5 Number of packages

7 Reference Documents

- 7.1 USP 37
- 7.2 Inhouse Indofarma

8 History

Purchasing specification is revision of RPB 175 revision 01 with change in the format document.

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9 Review

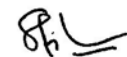

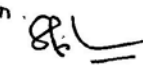


This specification will be reviewed every 2 years or less (if necessary) by the Quality Control Manager, Research & Development Manager and Quality Assurance Manager.

10 Distribution

In general, a copy of this specification is distributed to :

- 10.1 Procurement Dept.
- 10.2 Quality Control Dept.

11 Approval

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	AM		180213
Checked by	Analytical Method Assistant Manager	LB		180213
Approved by	Quality Control Manager	AM	^{an} 	180213
	Research & Development Manager	LB		180213
	Quality Assurance Manager	PM		180213

12 Review

No.	Position	Date	Signature	Recommendation
1	Quality Control Manager			
	Research & Development Manager			
	Quality Assurance Manager			
2	Quality Control Manager			
	Research & Development Manager			
	Quality Assurance Manager			